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VIA ECF
The Honorable Denise L. Cote
United States District Court Judge
Southern District of New York
500 Pearl Street, Room 1910
New York, New York 10007

***In Re: Acetaminophen ASD/ADHD Prods. Liab. Litig.*, 1:22-md-3043 (DLC)**
Letter Regarding FDA Response to Statement of Interest

Dear Judge Cote,

At the very first MDL conference in November 2022, Your Honor expressed the desire to "engage the FDA" in this matter for the sake of "the women of America and the doctors in America." November 17, 2022 Conference Transcript at 15:20. Your Honor did just that, and we now have the answer: the FDA believes that "the limitations and inconsistent findings of current observational studies of [acetaminophen] and neurobehavioral and urogenital outcomes are unable to support a determination of causality." The FDA's latest pronouncement reaffirms its prior statements on this question and confirms that Plaintiffs' lawyers, their advertising, and this litigation are creating a public health risk by scaring pregnant women about acetaminophen with no scientific basis.

It bears mention that the United States Attorney, in consultation with the FDA, reiterated this conclusion despite having access to Plaintiffs' one-sided characterization of Plaintiffs' litigation expert reports and deposition testimony, which Plaintiffs' leadership produced to the United States unsolicited, undisclosed, and in the midst of expert discovery. Defendants learned of Plaintiffs' August 31 letter to the United States for the first time upon receiving the United States' response and immediately asked for a copy (which Plaintiffs' counsel initially refused to provide).[1] The United States appropriately declined Plaintiffs' invitation to "submit a statement of interest opining that plaintiffs' experts' testimony should survive any *Daubert* motions" (DE 1105 at n. 1); however, it is instructive that FDA had access to this one-sided submission and still stands by its conclusion that, on the question of in utero exposure to acetaminophen and the risk of ASD or ADHD, the unbiased science does not support causation.

Acetaminophen is and remains one of the few medications available for treatment of pain and fever in pregnancy. Allowing this litigation to continue, in light FDA's express findings, poses the exact public health concern that the Court sought to mitigate by issuing its Invitation – alarming

[1] Plaintiffs claim that their decision to provide the letter now was "an effort to be fully transparent." It was nothing of the sort. If the United States had not specifically referenced the correspondence in its response, Defendants and the Court would never have known about its existence.

the public regarding use of medication in pregnancy and potentially leaving pregnant patients without treatment, contrary to medical advice and prevailing science.

We respectfully request an in-person status conference as soon as practical for Your Honor in order to discuss the path forward for this litigation in light of FDA's response.

Respectfully submitted,

/s/ Sarah E. Johnston

cc: All Counsel of Record (Via ECF)